REMARKS

Claim 1 has been amended and claim 8 has been canceled. Support for this amendment can be found at p. 6, l. 25-26.

A substituted specification is submitted herewith that address the Examiner's concerns about the use of the trademark "Maltidex H16323."

The drawings have been withdrawn. The drawings filed with the amendment dated 3 May 2003 are black and white photo prints of the original digital photographs. Because the original pictures were recorded digital it will not be possible to provide drawings of a quality better than what has already been filed. As the drawings are not necessary to a complete understanding of the invention as claimed, applicants submit that they are not necessary and therefore request that they be withdrawn from the application.

Rejections Under 35 USC § 112

In the previous Office Action, the Examiner rejected claims 1-14, 16-35, 39, 52-55 and 59 under 35 USC §112. In particular, the Examiner objected to the limitation in claim 1 that the recites "without prior dissolution or other reconstitution." Applicants note that this limitation was added at the suggestion of the Examiner, but more importantly that it is supported through out the specification. For Example, at p.4 line 15-17, the specification recites "to obtain a satisfactory solid-dose parenteral-injection, the composition to be injected must be of small volume to avoid injection pain and to achieve rapid dissolution." Clearly, this implies – to one of ordinary skill in the art – that the invention is not dissolved prior to injection. Moreover, the specification is replete

with examples that show the invention is a solid injectable and thus is not dissolved before injection. Applicants note that this fact was obvious to the Examiner in that the Examiner suggested the limitation after reading the specification. Accordingly, applicants respectfully submit that the claims are fully supported by the specification, even though the exact langauge of the claims is not recited verbatim in the specification.

The Examiner, in the previous Office Action also stated that the limitation of claim 1 requiring the invention to be needle shaped was indefinite. Applicants respectfully note the term needle is not indefinite in view of the field of the invention and, more importantly, in view of the specification. For example, the specification at p. 8, lines 22-24 describe a hypodermic needle shaped embodiment. Clearly, one of ordinary skill in the art is capable of discerning a needle having this shape. In addition, it is well-known that hypodermic needles may be cone shaped or cylindrically shaped. (See U.S. Patent Publication 2003-0009137-A1). Claim 9 further limits the shape of a needle to the cylindrical variety and is therefore not indefinite or duplicative of claim 1.

R jections Und r 35 USC §103

In the previous Office Action, the Examiner rejected the pending claims under 35 U.S.C § 103 in view of Roser et al. As amended, the present claims are neither anticipated nor obvious in view of Roser et al.

Roser et al. describes a pharmaceutical composition of a glassy matrix comprising a guest substance that may be a drug. The glassy matrix may comprise hydrophobically derivatized carbohydrates (HDC). The composition may be in the form of for example a powder of microneedles or microfibre or in the form of a needle.

Roser et al. states that "small delivery system size increase the comfort of administration" (p. 7, l. 15-16). Furthermore, Roser et al. discloses that "more than 20% weight percent of organic molecules can be incorporated into the HDC delivery systems" (p. 24, l. 29-31).

However, the maximal concentration of pharmaceutical active component usable with the invention is not disclosed. In particular, several different dosage forms are described, but it is not clear from the disclosure, which of said dosage forms may comprise >20% organic molecule.

On page 35, l. 25-27, Roser et al. states that "macroscopic glass needles of sufficient intrinsic strength may be directly driven in through the skin". The document does not disclose what is required in order to obtain a needle of "sufficient intrinsic strength", in particular it is nowhere disclosed what the ratio between HDC and organic molecule must be in order to obtain such a needle. Only example 5 describes how to prepare a macroscopic needle according to the invention. Said needle is a hollow fibre

of 100% HDC. The cavity of said fibre contains an HDC powder comprising a drug. The HDC powders described in the example comprises a maximum of 20% HDC.

Based on Roser et al. it would not have been obvious to the person skilled in the art that an HDC composition comprising more than 20% drug has the sufficient intrinsic strength to prepare a workable needle. In particular, since the invention only discloses a needle made of a hollow 100% HDC fibre, the person skilled in the art would anticipate, that a material with a high HDC fibre content is required to obtain a needle of the required strength (see enclosed declaration pursuant to 37 CFR 1.132).

Claim 1 has been amended in order to clarify that the therapeutic agent is distributed homogeneously throughout the compositions according to the present invention. Hence, in contrast to Roser et al. the present invention discloses a needle, wherein the therapeutic agent is distributed homogeneously and not a needle prepared from a hollow fibre.

In the previous Office Action the Examiner also rejected the pending claims under 35 USC §103, in view of Roser et al. and Bar-Shalom. The presently pending claims are not obvious in view of these references taken together.

Bar-Shalom describes a solid pharmaceutical composition capable of penetrating skin, wherein a material added endures the pharmaceutical composition with sufficient strength for injection. A wide variety of materials may be used such as protein, gelatin and carbohydrates. The document also discloses that the composition preferably consists essentially of the active drug substance itself (p. 6, l. 25 to p. 7, l. 4).

The document does not disclose how to obtain a pharmaceutical composition

with sufficient strength essentially consisting of an active drug. In contrast the document discloses that most drugs will not have the sufficient strength and that "the most common implementation comprises (of) a material to give strength" (p. 11, l. 14-15). The document is totally silent about the ratio between material and active drug. The pharmaceutical compositions described in the examples are based on gelatin and the drug content is not described.

Hence, based on Roser et al. in view of Bar-Shalom the person skilled in the art would have reached the conclusion, that it is **desirable** to obtain a pharmaceutical composition capable of penetrating skin comprising as much drug as possible. However said person would not have any knowledge of how to solve the technical problem of obtaining said composition based on Roser et al. alone or in view of Bar-Shalom.

Information disclosure statement

Applicants note that the Information Disclose Statement was filed was accompanied by a general authorization by Robert Smith to charge any fees to Deposit Account No. 19-2385. In fact, subsequent papers filed by Robert Smith also contained similar general authorizations. However, to expedite matters, the Commissioner is hereby authorized to charge the required fee to Deposit Account No. 14-1447, as well as any and all other fees due in connection with this application.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is hereby invited to contact the Applicant's attorney by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE
In the Claims

1. (Twice Amended) A solid pharmaceutical composition for parenteral injection, said composition having the shape of a needle capable of penetrating cutis or mucosa, comprising a binder and at least one therapeutic agent, said binder constituting at least 0.5% by weight of the composition and said binder comprising at least one binder agent being a carbohydrate, and said therapeutic agent comprising at least 25 % by weight of the composition and said composition comprising at least one non-crystallisation agent, whereby said binder forms an amorphous matrix, and whereby such composition is injectable without dissolution or other reconstitution and wherein, the therapeutic agent is distributed homogeneously throughout the composition.